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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/995,277

Applicant(s)

Baell et al.

Examiner

Phyllis Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 19, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 108-150 is/are pending in the application.
- 4a) Of the above, claim(s) 114, 115, 117-121, 143, 144, and 146-150 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 108-113, 116, 122-142, and 145 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 1/2 6) ☐ Other:

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Compounds of the formula of instant claims 108 and 122 wherein at least one of W^1 and W^2 is CO_2R_3 and the other is CO_2R_3 , $C(=NH)NH(OH)$ or $C(=O)CF_3$, and wherein no heteroaryl groups are present, in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in class 514, subclass 532+.
- II. Compounds of the formula of instant claims 108 and 122 wherein at least one of W^1 and W^2 is $PO(OR^3)_2$, in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in class 514, subclass 102+.
- III. Compounds of the formula of instant claims 108 and 122 wherein at least one of W^1 and W^2 is $C(=NH)NH(OH)$ and the other is not CO_2R^3 or $PO(OR^3)_2$, and wherein no heteroaryl moieties are present in the compound, in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in class 514, subclass 633.
- IV. Compounds of the formula of instant claims 108 and 122 wherein each of W^1 and W^2 are $C(=O)CF_3$ and no heteroaryl moieties are present in the compound, in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in class 514, subclass 675+.

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- IV. Compounds of the formula of instant claims 108 and 122 wherein Ar¹ and Ar² are independently heteroaryl and W¹ and W² are not PO(OR³)₂, in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in various subclasses of Class 514, depending on the heteroaryl moiety contemplated.
- V. Compounds of the formula of instant claims 108 and 122 that are not encompassed in any of the Groups supra in a method of inhibiting Fc receptor binding of immunoglobulin, and pharmaceutical compositions thereof, classified in various subclasses of Class 514.

The Groups are distinct, each from the other, for the following reasons:

The Groups have acquired a separate status in the art as shown by their different classifications and their recognized, divergent subject matter. The searches required for each Group are not co-extensive. Each Group is capable of supporting a separate patent. Thus restriction for examination purposes, as indicated, is proper.

Applicants' election with traverse of the compound of claim 116, designated BRI 6727, 3-[(m-carboxyphenyl)methoxy]benzoic acid, which is encompassed in Group I supra, filed February 19, 2002, Paper No. 6, is acknowledged. Applicants argue the claimed compounds represent a reasonable number of species that is sufficiently small and which are biologically related.

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Applicants' arguments have been given careful consideration but are not found persuasive.

The various compounds recited as inhibitors of Fc-receptor binding are selected from benzoic acids, aromatic compounds, heteroaromatic compounds, mono- and polycyclic compounds, amino acid derivatives, amidines, nucleosides and analogs thereof, optionally substituted with heterocyclic groups. The various compounds recited as Fc receptor binding inhibitors are repugnant to accepted principles of scientific classification. A plethora of compounds are encompassed within the definitions provided by the specification. The search required for one specific composition, for example, would vary from compound to compound. Distinctness of the methods is further evidenced by the different classification based on the many disclosed inhibitors of unrelated structure. Further, as to the burden of the search, classification is merely one indication of the burdensome nature of the required search. The literature search of the large number of possible inhibitors claimed herein is not necessarily co-extensive and is a major factor in determining the burden of the search.

A Preliminary Amendment filed November 26, 2001, Paper No. 2, is acknowledged.

Claims 1-107 are canceled. New claims 108-150 are presented and represent all of the claims now under consideration.

Claims 108-113, 116, 122-142 and 145, wherein the inhibitor is a compound as set forth in Group I supra, reflect the subject matter presently under consideration. Those compositions and methods of use comprising other compounds, claims 114, 115, 117-121, 143, 144 and 146-150, Groups II-V, are withdrawn from consideration by the Examiner as being drawn to non-elected

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inventions, 37 CFR 1.142(b). Affirmation of the election of Group I is requested when Applicants respond to this Office Action.

An Information Disclosure Statement filed November 26, 2001, Paper No. 2 ½, is acknowledged and has been reviewed.

Claims 108-112 and 122-141 are rejected under judicially created doctrine as being drawn to an improper Markush group. A proper Markush group must share a substantial structural feature disclosed as being essential. Lack of unity of invention has been found to exist since a common nucleus among the various Fc receptor inhibitors is absent. A prior art reference anticipating the claims under 35 U.S.C. 102 with respect to one species, such as for example, an amino acid derivative of the formula -C-C-N-, would not render the same claims obvious under 35 U.S.C. 103 with respect to another species such as a heterocyclic ring system. The members of the instant Markush group possess widely different properties and are not considered functionally equivalent.

Deletion of the non-elected subject matter would resolve the issue.

The claims will be examined fully with respect to the elected species only and further to the extent necessary to determine patentability. See MPEP 803.02.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 108-150 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-50 of U.S. Patent No. 6,355,683. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

Claims 108-111 and 122-141 are rejected under 35 U.S.C. 112, both first and second paragraphs, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make the invention, and, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

The metes and bounds of the term L cannot be precisely determined. The definition of the term as "a linker comprising from 1 to about 20 atoms" applies to a plethora of groups and lacks

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clarity. Numerous groups that lack enablement and an adequate teaching as to how to prepare them are encompassed in the language of the claims. Undue experimentation would be required to embrace the scope of the claims. Applicants should recite those linking groups contemplated.

Claim 113 recites the limitation "wherein L is $-\text{CH}_2\text{O}-$ ". There is insufficient antecedent basis for this limitation in claim 112. Claim 113 is rejected under 35 U.S.C. 112, second paragraph.

Claim 141 recites the limitation " L^1 ". There is insufficient antecedent basis for this limitation. Claim 141 is rejected under 35 U.S.C. 112, second paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 108-112 ^{3 and 116} are rejected under 35 U.S.C. 102(b) as being anticipated by Riad et al., J.

Chem. Res. Synop. (abstract), or Aizpurua et al., Can. J. Chem. (abstract).

Riad and Aizpurua independently disclose the compound 4,4'-[oxybis(methylene)] bis-benzoic acid, the compound of instant claim 116, in a composition.

No claim is allowed.

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Any inquiry concerning this communication should be directed to Phyllis Spivack at
telephone number 308-4703.

May 14, 2002

Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**